

§ 522.1315 Maropitant.

(a) *Specifications.* Each milliliter of solution contains 10 milligrams (mg) maropitant as maropitant citrate.

(b) *Sponsor.* See No. 000069 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Dogs*—(i) *Amount.* Administer 1.0 mg per kilogram (mg/kg) of body weight by subcutaneous injection once daily for up to 5 consecutive days.

(ii) *Indications for use.* For the prevention and treatment of acute vomiting.

(iii) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) *Cats*—(i) *Amount.* Administer 1.0 mg/kg of body weight by subcutaneous injection once daily for up to 5 consecutive days.

(ii) *Indications for use.* For the treatment of vomiting.

(iii) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[72 FR 9243, Mar. 1, 2007, as amended at 77 FR 39391, July 3, 2012]

§ 522.1335 Medetomidine hydrochloride injection.

(a) *Specifications.* Each milliliter of sterile aqueous solution contains 1.0 milligram of medetomidine hydrochloride.

(b) *Sponsor.* See 052483 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Amount.* 750 micrograms intravenously (IV) or 1,000 micrograms intramuscularly per square meter of body surface. The IV route is more efficacious for dental care.

(2) *Indications for use.* As a sedative and analgesic in dogs over 12 weeks of age to facilitate clinical examinations, clinical procedures, minor surgical procedures not requiring muscle relaxation, and minor dental procedures not requiring intubation. The intravenous route of administration is more efficacious for dental care.

(3) *Limitations.* Do not use in dogs with cardiac disease, respiratory disorders, liver or kidney diseases, dogs in shock, dogs which are severely debilitated, or dogs which are stressed due to extreme heat, cold, or fatigue. Allow agitated dogs to rest quietly before ad-

ministration. Do not repeat dosing in dogs not responding satisfactorily to treatment. Do not use in breeding or pregnant animals. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[61 FR 21075, May 9, 1996]

§ 522.1350 Melatonin implant.

(a) *Specifications.* The drug is a silicone rubber elastomer implant containing 2.7 milligrams of melatonin.

(b) *Sponsor.* See No. 053923 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Amount.* One implant per mink.

(2) *Indications for use.* For use in healthy male and female kit and adult female mink (*Mustela vison*) to accelerate the fur priming cycle.

(3) *Limitations.* For subcutaneous implantation in mink only. Do not implant potential breeding stock. Do not use in food-producing animals.

[59 FR 37422, July 22, 1994]

§ 522.1362 Melarsomine dihydrochloride for injection.

(a) *Specifications.* The drug consists of a vial of lyophilized powder containing 50 milligrams of melarsomine dihydrochloride which is reconstituted with the provided 2 milliliters of sterile water for injection.

(b) *Sponsor.* See No. 050604 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Amount.* For asymptomatic to moderate (class 1 to class 2) heartworm disease: 2.5 milligrams per kilogram of body weight (1.1 milligram per pound) twice, 24 hours apart. The series can be repeated in 4 months depending on the response to the first treatment and the condition, age, and use of the dog. For severe (class 3) heartworm disease: Single injection of 2.5 milligrams per kilogram followed, approximately 1 month later, by 2.5 milligrams per kilogram administered twice, 24 hours apart.

(2) *Indications.* Treatment of stabilized, class 1, 2, and 3 heartworm disease (asymptomatic to mild, moderate, and severe, respectively) caused by immature (4 month-old, stage L₅) to mature adult infections of *Dirofilaria immitis* in dogs.